

## CLAIMS

I claim:

1. A body analyte monitoring device comprising

- a) a microdialysis needle with an inlet port and an outlet port
- b) a reservoir containing a perfusate in fluid communication with said inlet port of said microdialysis needle
- c) the outlet port of said microdialysis needle in fluid communication with an analysis compartment wherein said body analyte acquired by said microdialysis needle may be assayed
- e) pumping means to move said perfusate from said reservoir into said inlet port of said microdialysis needle, through said microdialysis needle, out of said outlet port of said microdialysis needle, and into said analysis compartment
- d) a reservoir containing a body analyte calibration fluid in fluid communication with said analysis compartment
- e) pumping means to move said calibration fluid from said calibration fluid containing reservoir into said analysis compartment
- f) a reservoir containing a reagent solution in fluid communication with said analysis compartment

g) pumping means to move said reagent solution from said reagent solution reservoir into said analysis compartment

h) fluid sequencing means whereby the fluid moving into said analysis compartment may be selected as either said perfusate from said outlet port of said microdialysis needle mixed with said reagent solution or said calibration fluid mixed with said reagent solution.

2. The device of the claim 1 wherein said microdialysis needle is placed in contact with interstitial fluid of an animal.

3. The device of claim 2 wherein said microdialysis needle comprises a semipermeable membrane along one face of said microdialysis needle such that said semipermeable membrane is interposed between said interstitial fluid of an animal and the lumen of said microdialysis needle such that said body analyte passes from said interstitial fluid into said lumen.

4. The device of claim 3 wherein said semipermeable membrane is comprised of permeable polysilicon.

5. The device of claim 2 wherein the body analyte monitoring device is worn on the body in contact with the skin.

6. The device of claim 5 wherein body contact is maintained with a skin adhesive or a strap.
7. The device of claim 1 wherein said pumping means is a positive displacement pump or a pressurized reservoir or a piezoelectric pump.
8. The device of claim 1 wherein said microdialysis needle is made of silicon and in part fabricated using a silicon etch process.
9. The device of claim 1 wherein the cross-sectional area of the lumen of the microdialysis needle is less than 5000 square microns
10. The device of claim 1 wherein the width to height ratio of the cross-sectional area of the lumen of the microdialysis needle is larger than 1.5:1
11. The device of claim 2 wherein said body analyte is glucose.
12. The device of claim 11 in combination with a means for administering insulin.
13. The device of claim 12 wherein measurements of glucose are used to control the delivery of insulin from said means for administering insulin to said animal.

14. The device of claim 1 wherein the assay conducted in said analysis chamber is a measurement of an optical property of either the body analyte laden perfusate or the calibration fluid after mixing and reaction with said reagent solution.

15. The device of claim 1 wherein the assay conducted in said analysis chamber is a measurement of the viscosity of the body analyte laden perfusate or the calibration fluid after mixing and reaction with said reagent solution.

16. The device of claim 1 wherein the assay conducted in said analysis chamber is an electrochemical measurement of the body analyte laden perfusate or the calibration fluid after mixing and reaction with said reagent solution.

17. A periodic body analyte monitoring device comprising

- a) a microdialysis needle with an inlet port and an outlet port
- b) a reservoir containing a perfusate in fluid communication with said inlet port of said microdialysis needle
- c) the outlet port of said microdialysis needle in fluid communication with an analysis compartment wherein said body analyte may be assayed
- c) pumping means to move said perfusate from said perfusate reservoir into said inlet port of said microdialysis needle, through said microdialysis needle, and out of said outlet port of said microdialysis needle, and into said analysis compartment
- d) a reservoir containing a solution of an enzyme specific for said body analyte in fluid communication with said analysis compartment

e) pumping means to move said enzyme solution from said enzyme solution reservoir into said analysis compartment

f) a reservoir containing a body analyte calibration fluid in communication with said analysis compartment

g) pumping means to move said calibration fluid from said calibration fluid containing reservoir into said analysis compartment

h) fluid sequencing means whereby the fluid moving into said analysis compartment can be selected as either said perfusate mixed with said enzyme solution or said calibration fluid mixed with said enzyme solution.

18. The device of the claim 17 wherein said microdialysis needle is placed in contact with interstitial fluid of an animal.

19. The device of claim 18 wherein said microdialysis needle comprises a semipermeable membrane along one face of said microdialysis needle such that said semipermeable membrane is interposed between said interstitial fluid of an animal and the lumen of said microdialysis needle such that said body analyte passes from said interstitial fluid into said lumen.

20. The device of claim 21 wherein said semipermeable membrane is comprised of permeable polysilicon.

21. The device of claim 17 wherein the periodic body analyte monitoring device is worn on the body in contact with the skin

22. The device of claim 21 wherein body contact is maintained with a skin adhesive or a strap.

23. The device of claim 17 wherein said pumping means is a positive displacement pump or a pressurized reservoir or a piezoelectric pump.

24. The device of claim 17 wherein said microdialysis needle is made of silicon and in part fabricated using a silicon etch process.

25. The device of claim 17 wherein the cross-sectional area of the lumen of said microdialysis needle is less than 5000 square microns

26. The device of claim 17 wherein the width to height ratio of the cross-sectional area of the lumen of said microdialysis needle is larger than 1.5:1

27. The device of claim 18 wherein said body analyte is glucose

28. The device of claim 27 in combination with a means for administering insulin.

29. The device of claim 28 wherein measurements of glucose are used to control the delivery of insulin from said means for administering insulin to said animal.

30. A method of calibrating a body analyte monitoring microdialysis device comprising alternating the flow of a body analyte laden perfusate mixed with an appropriate reagent and a body analyte containing calibration fluid mixed with said appropriate reagent into an analysis compartment wherein a result of a reaction between said appropriate reagent and the body analyte in said body analyte containing perfusate or calibration fluid is measured.

31. The method of claim 30 wherein at least one portion of said body analyte containing calibration fluid mixed with said appropriate reagent enters said analysis compartment before a portion of said body analyte containing perfusate mixed with said appropriate reagent enters said analysis compartment.